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| 09/894,174      | 06/27/2001  | William M. Blackshear JR. |                     | 5327             |

97101 7590 12/15/2011  
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| EXAMINER |
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RINES, ROBERT D

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| ART UNIT | PAPER NUMBER |
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3623

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12/15/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/894,174 | <b>Applicant(s)</b><br>BLACKSHEAR ET AL. |  |
|                              | <b>Examiner</b><br>DAVID RINES       | <b>Art Unit</b><br>3623                  |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 5) ☒ Claim(s) 19 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 19 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

[1] A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 November 2011 has been entered.

### ***Notice to Applicant***

[2] This communication is in response to the Response and the Request for Continued Examination (RCE) filed 23 November 2011. Claim 19 is pending.

### ***Claim Rejections - 35 USC § 112/Claim Rejections - 35 USC § 101***

[3] The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[4] 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requires of this title.

[5] Claim 19 recites both components of an apparatus/machine and independent method steps absent a designated apparatus/machine component to which the actions/steps are attributable. Further, the claim recites process steps which are attributable to actions performed by a human operator and do not utilize the system components. Claim 19 is therefore directed to both a machine/apparatus (i.e., a product) and a process/method (i.e., a process).

Under 35 U.S.C. 101, the claimed invention must fall into one of the four recognized statutory classes of invention, namely, a process (or method); a machine (or system); an article of manufacture; or a composition of matter. The claimed invention must be directed to a single statutory class of invention. See MPEP §2173.05(p), which states that a single claim must be drawn to either a product or process (but not both) and because a potential competitor of Applicant(s) would not know whether possession alone of the claimed structure constituted infringement, or alternatively, if infringement required the execution of the recited method steps, the claims are indefinite.

Specifically, it is unclear as to which statutory class of invention the claim is directed. For purposes of applying art, Examiner assumes claim 19 to be directed to a machine/apparatus (i.e., a "product").

Considered as a product claim, claim 19 identifies the system components as “..a network of remotely operated computers from healthcare facilities, an evaluating authority and accredited laboratory...”. This recitation, provided in the preamble of the claim, fails to specifically define the system structure such that the claimed structure of the claimed system is clearly defined. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, (1) it is not clear as to which statutory class of invention the claimed invention is directed and (2) when considered as a machine/apparatus, the claim fails to specifically define the structure of the claimed apparatus.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

[6] Claims 1-18 have been cancelled.

[7] Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crutchfield (United States Patent #6,699,193).

NOTE: As discussed above, claim 19 is a hybrid claim incorporating both apparatus elements and independent method steps. Claim 19 has been interpreted for examination purposes as directed to a machine or apparatus, as designated by the preamble of the claim (see rejection(s) under 35 U.S.C. 112, second paragraph, above). The preamble of claim 19 further identifies the machine components as "...a network of remotely located computers...". The limitations presented in the body of the claim further exclusively utilize the computers/network in a series of storage and transmission steps in which patient vascular and surgical assessment data is transmitted between computers located at different facilities. The computers, i.e., system components, are not utilized in the accompanying assessment and evaluation steps, but rather the steps are carried out by human operators and merely identify an intended use for the data. For example, claim 19 recites "...receiving and storing the collected data in the computer....*to review and compare said collected data against medically accepted criteria...*". The recited "review and compare..." assessment is directed to an intended use of the transmitted and stored patient data and therefore does not alter the structure of the recited system. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The applied passages of Crutchfield disclose a network of remotely located computers, and accordingly, provide the structure of the claimed system. As it is unclear whether Applicant intends to claim a machine/apparatus or process/method, in the interest of advancing prosecution, Examiner has cited relevant sections of Crutchfield in which the claimed assessment and evaluation steps are performed. However, Examiner maintains that these applied teachings are not required by the claim as presented for the reasons set forth above.

As per claim 19, Crutchfield et al. disclose a classification and management system for patients with lower extremity arterial occlusive disease comprising a network of remotely located computers from healthcare facilities, entering and storing collected patient data of physically observable conditions of the patient's lower extremities and noninvasive arterial pressure and blood flow data in the memory of a computer at the healthcare facility (Crutchfield et al.; col. 9, lines 24-29 and lines 30-39), transmitting said collected patient data from the healthcare facility computer to a computer at an evaluating authority (Crutchfield et al.; col. 9, lines 24-29 and lines 30-39), recording the collected patient data (Crutchfield et al.; col. 9, lines 24-29 and lines 30-39, col. 17, lines 17-28 and lines 65-67, and col. 18, lines 1-14), transmitting said collected patient data to an evaluating authority (Crutchfield et al.; col. 5, lines 34-57, col. 16, lines 54-67, and col. 17, lines 1-8), comparing said collected patient data against a medically accepted set of disease specific criteria at the evaluating authority to classify patients "potentially at risk" and those patients "not at risk" of developing complications of arterial occlusive disease (Crutchfield et al.; col. 9, lines 25-50), transmitting said preliminary classification to the healthcare facility (Crutchfield et al.; col. 5, lines 34-57, col. 16, lines 54-67, and col. 17, lines 1-8), referring those

patients classified as "potentially at risk" of arterial of arterial occlusive disease to an accredited laboratory for noninvasive vascular evaluation (Crutchfield et al.; col. 9, lines 14-52), evaluating those "potentially at risk" patients at the accredited laboratory against medically accepted criteria (Crutchfield et al.; col. 6, lines 22-39, col. 9, lines 14-52, and col. 19. lines 50-67), recording the results of said noninvasive vascular evaluation at the accredited laboratory (Crutchfield et al.; col. 9, lines 24-29 and lines 30-39, col. 17, lines 17-28 and lines 65-67, and col. 18, lines 1-14), transmitting said recorded results to the evaluating authority for final classification (Crutchfield et al.; col. 5, lines 34-57, col. 16, lines 54-67, and col. 17, lines 1-8), classifying each patient at the evaluating authority against medically accepted criteria as "at risk" or "not at risk" of developing arterial occlusive disease (Crutchfield et al.; col. 9, lines 40-52 and col. 10, lines 6-20), transmitting said "at risk" or "not at risk" patient final classification to the healthcare facility (Crutchfield et al.; col. 5, lines 34-57, col. 16, lines 54-67, and col. 17, lines 1-8), recording said "at risk" or "not at risk" patient final classification at the healthcare facility (Crutchfield et al.; col. 9, lines 24-29 and lines 30-39, col. 17, lines 17-28 and lines 65-67, and col. 18, lines 1-14), referring patient having a final classification of "at risk" for critical ischemia with associated extremity lesions and patients with and patient with noninvasive evidence of severe ischemia to a vascular surgery facility for vascular surgical assessment to determine whether revascularization is necessary (Crutchfield et al.; col. 6, lines 22-39, col. 9, lines 14-52, and col. 19. lines 50-67), assessing such "at risk" patients against medically accepted criteria as "clinical indication for operation" or "no indication for operation" at the vascular surgery facility (Crutchfield et al.; col. 6, lines 22-39, col. 9, lines 14-52, and col. 19. lines 50-67), electing revascularization and periodic management system evaluation at the healthcare facility or routing wound care and



periodic reevaluation at the healthcare facility by patients assessed as "clinical indication for operation" (Crutchfield et al.; col. 5, lines 34-57, col. 16, lines 54-67, and col. 17, lines 1-8), monitoring patients assessed as "no indication for operation" by the healthcare facility with increased precautions to monitor for detection of any visible deterioration of the patient's lower extremities that would require reassessment (Crutchfield et al.; col. 19, lines 50-67) referring patient having ulcers, pain, or gangrene at the time of "no indication for operation" assessment for reassessment (Crutchfield et al.; col. 09, lines 50-67), referring patients classified as "no indication for operation" that develop ulcers, pair and/or gangrene to the vascular surgery facility for reassessment (Crutchfield et al.; col. 09, lines 50-67), reassessing the referred patient at the vascular surgery facility against medically accepted criteria as "no indication for operation" or "clinical indication for operation" (Crutchfield et al.; col. 19, lines 50-67 and col. 20, lines 21-40), transmitting the reassessment of "no indication for operation" or "clinical indication for operation" to the evaluating authority for reevaluation as "no indication for operation" or "clinical indication for operation" (Crutchfield et al.; col. 17, lines 17-28 and lines 65-67, and col. 18, lines 1-14), transmitting the reevaluation to the healthcare faculty with the appropriate medical procedure and regimen (Crutchfield et al.; col. 5, lines 34-57, col. 16, lines 54-67, and col. 17, lines 1-8), treating and monitoring patients classified as "not at risk", " at risk" and assessed as "no indication for operation" or "clinical indication for operation" at the healthcare facility (Crutchfield et al.; col. 46, lines 29-67 and col. 47, lines 23-62), providing "not at risk" patient without limb ulcers routing care and precautions at the healthcare facility (Crutchfield et al.; col. 46, lines 29-67 and col. 47, lines 23-62), providing "not at risk" patient with limb ulcers routine wound care at the healthcare facility (Crutchfield et al.; col. 46, lines 29-67 and col. 47,

lines 23-62), providing "not at risk" patient with limb ulcers periodic reevaluation by the evaluating authority (Crutchfield et al.; col. 6, lines 22-39, col. 9, lines 14-52, and col. 19, lines 50-67), providing "at risk" patients assessed as "no indication for operation" or "operation not elected by patient" and "clinical indication for operation" patient undergoing revascularization at the vascular surgery facility with intensive wound care at the healthcare facility (Crutchfield et al.; col. 46, lines 29-67 and col. 47, lines 23-62), and providing periodic reevaluations of "at risk" patient assessed as "no indication for operation" or "operation not elected by patient" with increased precautions at the healthcare facility (Crutchfield et al.; col. 6, lines 22-39, col. 9, lines 14-52, and col. 19, lines 50-67).

Crutchfield et al. disclose a system including a network of computers to perform the disclosed steps/functions (Crutchfield et al.; Abstract, col. 6, lines 20-39, and col. 9, lines 15-30).

While Crutchfield et al., does not exemplify precisely the patient diagnosis and treatment scenario presented by claim 19 as presently amended, Crutchfield provides the functionality required to enable each of the "assessment" "reassessment" and "treatment" steps defined by claim 19 including the transmission of data and the referral of patients presenting a particular set of symptoms for appropriate treatment. Accordingly, a medical institution and associated staff practicing the Crutchfield et al. invention in the treatment of individuals with vascular disease would achieve the method defined by claim 19 as a result of user selections (i.e., user choices) made during the course of practicing physicians (i.e., diagnosing and treating patients for vascular disease).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the system and method of Crutchfield et al. to accomplish the method steps defined by claim 19. One of ordinary skill in the art would have been motivated to do so by the desire to assess the vascular health of a patient in order to assess the effects of treatments, risk factors and substances, including therapeutic substances, on blood vessels by measuring various parameters of blood flow in one or more vessels and analyzing the results in a defined manner (Crutchfield et al.; col. 1, lines 25-30).

***Response to Remarks***

[8] Applicant's remarks filed 23 November 2011 have been fully considered but they are not persuasive. In the remarks filed 23 November 2011, Applicant provides no additional arguments with respect to the rejection(s) of claim 19. Accordingly, the remarks are reasonably considered to have been address in the preceding sections the instant Office Action and in the previous Office Actions mailed 5 October 2010, 30 December 2009, and 17 March 2009 hereby incorporated by reference.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID RINES whose telephone number is (571)272-5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Beth Boswell can be reached on 571-272-6737. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. David Rines/  
Primary Examiner, Art Unit 3623